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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, v. KINRAY, LLC, Defendant.	16 Civ. 9767 **COMPLAINT**

Plaintiff, the United States of America, by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, alleges upon information and belief as follows:

INTRODUCTION

1. The United States of America brings this civil enforcement action seeking penalties and injunctive relief against defendant for violating the Controlled Substances Act, as amended, 21 U.S.C. §§ 801 *et seq.* (the "Act" or "CSA"), and its implementing regulations, 21 C.F.R. §§ 1301 *et seq.* (the "Regulations"). As set forth more fully below, the United States alleges in this action that defendant Kinray, Inc. ("Kinray"), a controlled substances distributor

headquartered in Whitestone, New York, engaged in repeated violations of the Act and Regulations with regard to the filing of required Schedule II suspicious order reports and related records.

JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. §§ 842(c)(1) and 843(f)(2), and 28 U.S.C. §§ 1345 and 1355.

3. Venue is proper in the Southern District of New York pursuant to 21 U.S.C. § 843(f)(2) and 28 U.S.C. §§ 1391(b) and 1395(a).

THE PARTIES

4. Plaintiff is the United States of America.

5. Defendant Kinray is a pharmaceutical distributor located in Whitestone, Queens, New York. Kinray engages in interstate distribution of, among other things, controlled substances as defined under the Act, pursuant to a registration number issued by the Drug Enforcement Administration ("DEA"). *See* 21 U.S.C. § 802(6); 21 C.F.R. § 1308.12. Kinray regularly distributes scheduled controlled substances to pharmacies that conduct business in the Southern District of New York.

REGULATORY BACKGROUND

6. Drugs and other substances that are considered controlled substances under the CSA are divided into five "schedules," generally designated by Roman numerals I through V. Schedule II controlled substances, as defined under the Act, are drugs that have a currently accepted medical use in the United States, but also a high potential for abuse, which may lead to severe psychological or physical dependence. *See* 21 U.S.C. § 812(b)(2).

7. To combat the high potential for abuse of Schedule II controlled substances, the Act creates a distribution monitoring system for those authorized to handle controlled substances, at the heart of which are registration, tracking, and reporting requirements. The Act mandates strict adherence to a number of these requirements by any person or entity that distributes controlled substances.

8. A distributor is a person or an entity that delivers (other than by administering or dispensing) a controlled substance. Delivery is the actual, constructive, or attempted transfer of a controlled substance. *See* 21 U.S.C. §§ 802(8), (11).

9. Among the requirements for a person or entity that distributes controlled substances is mandatory reporting of suspicious orders of controlled substances. Specifically, distributors of controlled substances must design and operate a system to disclose suspicious orders of controlled substances, and report any discovered suspicious orders to the DEA. *See* 21 C.F.R. § 1301.74(b). Suspicious orders include "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." *Id*.

10. DEA's suspicious order reporting requirements for controlled substances are an integral part of its efforts to track the illicit distribution of narcotics and other dangerous drugs.

11. Violations of requirements under the Act carry a per-violation penalty of up to $10,000, as well as injunctive relief. *See* 21 U.S.C. §§ 842(c)(1)(B) and 843(f).

FACTS

12. Pursuant to the Act, DEA's New York Field Division regularly conducts audits and inspections of registered facilities, including distributors and pharmacies.

13. During the period between January 1, 2011 and May 14, 2012 (the "Relevant Period"), DEA investigated pharmacies in New York City and elsewhere that it determined had

ordered from distributor Kinray shipments of oxycodone or hydrocodone (both Schedule II controlled substances) that were of unusual size and/or unusual frequency.

14. During the Relevant Period, DEA identified shipments by Kinray of oxycodone or hydrocodone to more than 20 New York-area pharmacy locations that ordered a quantity of controlled substances that was many times greater than Kinray's average sales of controlled substances to all of its customers.

15. During this same time period, through its investigation, DEA's New York Field Division identified numerous orders containing "red flags" that Kinray ignored, including unusually large orders shipped to New York-area pharmacies. There was no apparent evidence that Kinray conducted due diligence with respect to these suspicious orders.

16. In fact, during most of the Relevant Period, Kinray did not report *any* suspicious order reports to DEA.

FIRST CAUSE OF ACTION

(Failure to Report Suspicious Orders – Multiple Violations)

17. Between January 1, 2011 and May 14, 2012, Kinray failed to adequately operate a system designed to disclose suspicious orders of controlled substances and report suspicious orders to DEA when discovered, in violation of the suspicious order reporting requirement codified at 21 U.S.C. § 842(a)(5) and 21 C.F.R. § 1301.74(b).

18. This violation occurred on multiple occasions, with the precise number of violations to be established at trial.

19. Each violation set forth above is subject to a penalty of up to $10,000.

WHEREFORE, the United States demands judgment in its favor and against Kinray as follows:

(a) for a maximum statutory penalty in the amount of $10,000 for each of the violations set forth herein pursuant to 21 U.S.C. § 842(c)(1)(B);

(b) for appropriate injunctive relief pursuant to 21 U.S.C. § 843(f);

(c) for the costs of this action; and

(d) for such further relief as the Court may deem proper.

Dated: New York, New York
December 19, 2016

PREET BHARARA
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Attorney for the United States of America

By: _____

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